BC Centre for Disease Control
An agency of the Provincial Health Services Authority

Adverse Event Following Immunization (AEFI)
Case Report Form

INSTRUCTIONS

- **Complete this reporting form for AEFIs which have a temporal association with a vaccine and which cannot be clearly attributed to other causes. For Temporal Reporting Criteria by Event see Section H, Page 6 of this form.**
- **Public health staff: Enter into Panorama or PARIS.**
- **Community vaccine providers: Submit the completed form to public health. See the AEFI reporting map here for directions on where to send the form according to health authority.**
- **For additional information on reporting criteria, clinical management and interpretation of AEFIs, and implications for subsequent immunization, please refer to BC Immunization Manual, Part 5 – Adverse Events Following Immunization**

Panorama Data Entry Guidance

More details in Section I, page 7.

REPORTER INFORMATION

Setting: ☐ Physician office ☐ Public health ☐ Hospital ☐ Other, specify:

Name: *Last* *First*

Phone Number: ( ) - ext.

Email:

Fax Number ( ) -

Address:

Branch Office: *(if applicable)*

Province/Territory: BC

Postal code:

Date reported: *YYYY / MM / DD*

Signature:

☐ MD ☐ RN ☐ IMPACT ☐ Pharmacist ☐ Other, specify:

Reported to public health unit by: ☐ Reporter ☐ Client ☐ Other, complete section A.

Reporter is the health care provider who received and reported the AEFI information to the health unit.

Defaults to the logged in user. To change, select 'Find' and search by last name.

A. SOURCE OF INFORMATION

Only complete Section A if "Other" selected for "Reported to public health unit by"

Name: *Last* *First*

Phone Number: ( ) - ext.

Email:

Relationship to client:

Address: *Unit #* *Street #* *Street Name* *City*

Postal Code:

Province: BC

Source of information can be the same as reporter, the client, or a secondary source such as a parent/guardian.

B. CLIENT INFORMATION

Name: *Last* *First* *Middle*

Date of Birth: *YYYY / MM / DD*

Gender: ☐ Male ☐ Female ☐ Transgender ☐ Unknown

Health Card Number:

Alternate Name(s):

Phone Number (home/work/mobile): ( ) - ext.

Address: *Unit #* *Street #* *Street Name* *City*

Postal Code:

Province: BC

Country of Residence (*if not Canada*):

Address Located on Reserve Administered By:

ADVERSE EVENT ID:

IMPACT LIN:

PARIS ID:

PATIENT'S PHYSICIAN (OR PRIMARY CARE PROVIDER)

Name: *Last* *First*

Phone Number ( ) - ext.

Address:

Record or review and update in >Subject >>Client Details >>>Personal Information

Enter IMPACT Local Inventory Number if the report was received from IMPACT; otherwise leave it blank.

Adverse Event Following Immunization (AEFI)
Case Report Form

	Panorama Data Entry Guidance

C. IMMUNIZATION DATA

Immunizing agent	Trade name	Manufacturer	Lot number	Dose #	Dosage/unit	Route	Site

An immunization record is required to create an AEFI report.

If the immunization record has not been entered in Panorama, you will first need to create it.

Refer to the Panorama Immunization Data Entry Guide on how to create a new immunization record.

D. INFORMATION AT TIME OF IMMUNIZATION AND AEFI ONSET

Province/Territory of immunization: BC

Age at onset:

Date vaccine administered: *YYYY / MM / DD*

(hr: ☐am / ☐pm)

Health Care Provider who administered the vaccine:

Phone: ( )

Address:

Unit # *Street #* *Street Name* *City*

Did an AEFI follow a previous dose of any of the above immunizing agents listed in section B?

☐ No ☐ Not applicable (no prior doses) ☐ Unknown ☐ Yes (If **yes**, provide details in section G.)

Did this AEFI follow an incorrect immunization?

☐ No ☐ Unknown ☐ Yes (If **yes**, choose all that apply and provide details in section G.):

☐ Given outside the recommended age limits ☐ Product expired ☐ Dose exceeded that recommended for age

☐ Wrong vaccine given ☐ Incorrect route ☐ Other, specify:

Medical history (up to time of AEFI onset). Check all that apply and provide details in section G.

☐ Concomitant medication(s) ☐ Known medical conditions/allergies ☐ Acute illness/injury

☐ Unknown at time of report ☐ Information not available

Use the section specific comment fields to report details in Panorama.

Please refer to Panorama AEFI Data Entry Guide for more information on the types of details to report.

If there is no medical history relevant to this event, enter "No medical history found" in comments (No. 17).

Report "Unknown at time of report" or "Information not available" in comment field No. 17.

E. AEFI DETAILS: Complete all sections as appropriate. For each check all signs/symptoms that apply. Item(s) with asterisk (*) should be diagnosed by a physician. If not, provide sufficient information to support the selected item(s). Use Section G for additional information including clinical details and test results.

Local reaction at or near injection site

Onset: Min. Hrs. Days from immunization to onset of 1st symptom/sign

Duration: Min. Hrs. Days from 1st symptom/sign to resolution of all symptoms/signs ☐ Unresolved

☐ Infected abscess* ☐ Sterile abscess* ☐ Cellulitis* ☐ Nodule ☐ Rash

☐ Pain, redness, or swelling extends past the nearest joint ☐ Adenopathy/Lymphadenitis*

☐ Pain or redness or swelling persisting for 10 days or more ☐ Other, specify:

For any injection site reaction indicated above, check all that apply and provide details in section G:

☐ Swelling ☐ Pain ☐ Tenderness ☐ Erythema ☐ Warmth ☐ Induration

Specify largest diameter of vaccination site reaction (cm): _____ Site(s) of reaction (e.g.,. LA, RA): _____

☐ Palpable fluctuance ☐ Fluid collection shown by imaging technique (e.g., MRI, CT, ultrasound)

☐ Spontaneous/surgical drainage ☐ Microbial results, specify ☐ Lymphangitic streaking ☐ Regional lymphadenopathy

Select a local reaction before selecting corresponding descriptors.

For tips on reporting rash see Section I. Report 'localized rash at the injection site' as "Other, specify" and select "Rash" as a sign.

For tips on reporting pain, redness, or swelling see Section I.

Report 'Adenopathy/ Lymphadenitis' as 'Lymphadenitis'.

Specify Microbial results in comment box (No. 23).

Adverse Event Following Immunization (AEFI)
Case Report Form

Panorama Data Entry Guidance

E. AEFI DETAILS *continued*

Anaphylaxis and other allergic events

Onset: Min. Hrs. Days from immunization to onset of 1st symptom/sign

Duration: Min. Hrs. Days from 1st symptom/sign to resolution of all symptoms/signs ☐ Unresolved

☐ Anaphylaxis ☐ Oculo-Respiratory Syndrome (ORS) ☐ Other allergic events

For the event indicated above, select all symptoms/signs that apply.

Skin/mucosal:
- ☐ **Generalized:** ☐ At injection site ☐ Non-injection site ☐ Urticaria ☐ Erythema ☐ Pruritus ☐ Prickly sensation ☐ Rash
- ☐ **Localized:** ☐ At injection site ☐ Non-injection site ☐ Urticaria ☐ Erythema ☐ Pruritus ☐ Prickly sensation ☐ Rash
- **Eye(s):** ☐ Red bilateral ☐ Red unilateral ☐ Itchy
- **Angioedema:** ☐ Tongue ☐ Throat ☐ Uvula ☐ Larynx ☐ Lip ☐ Eyelids ☐ Face ☐ Limbs ☐ Other, specify:

Cardiovascular: ☐ Measured hypotension ☐ ↓ central pulse volume ☐ Capillary refill time >3 sec ☐ Tachycardia ☐ ↓ or loss of consciousness:

Respiratory: ☐ Sneezing ☐ Rhinorrhea ☐ Hoarse voice ☐ Sensation of throat closure ☐ Stridor ☐ Dry cough ☐ Tachypnea ☐ Wheezing ☐ Increased use of accessory muscles ☐ Indrawing/retractions ☐ Grunting ☐ Cyanosis ☐ Sore throat ☐ Difficulty swallowing ☐ Difficulty breathing ☐ Chest tightness

Gastrointestinal: ☐ Diarrhea ☐ Abdominal pain ☐ Nausea ☐ Vomiting

Laboratory: ☐ Mast cell tryptase elevation > upper normal limit

Select "Anaphylaxis" or "Other allergic events" before selecting corresponding descriptors

For tips on reporting rash see Section I.

"Oculo-Respiratory Syndrome" and associated descriptors reported under "Other severe or unusual events".

Report "Angioedema > Face" as "Angioedema > Other, specify".

Use comment field No. 34 for additional signs or symptoms that are anaphylactic/ allergic in nature and are not listed (i.e., sore throat, difficulty swallowing, difficulty breathing, chest tightness, increased use of accessory muscles, MCT elevation).

If a client only reports GI symptoms, report under "Other severe or unusual events".

Neurologic event

Onset: Min. Hrs. Days from immunization to onset of 1st symptom/sign

Duration: Min. Hrs. Days from 1st symptom/sign to resolution of all symptoms/signs ☐ Unresolved

☐ **Seizure(s) (Check all that apply):**
- ☐ Febrile ☐ Afebrile ☐ Unknown type
- ☐ Focal
- ☐ Generalized: ☐ Tonic ☐ Clonic ☐ Tonic-clonic ☐ Atonic ☐ Myoclonic ☐ Absence
- ☐ Witnessed by health care professional: ☐ Yes ☐ No ☐ Unknown
- ☐ Sudden loss of consciousness: ☐ Yes ☐ No ☐ Unknown
- ☐ Previous history of seizures: ☐ Febrile ☐ Afebrile ☐ Unknown type

☐ **Meningitis*** ☐ **Encephalopathy/Encephalitis*** ☐ **Guillain-Barre Syndrome (GBS)*** ☐ **Bell's Palsy***

☐ **Anaesthesia/Paraesthesia (Check all that apply):**
- ☐ Generalized ☐ Localized
- ☐ Numbness ☐ Tingling ☐ Burning ☐ Formication ☐ Other, specify:

☐ **Other paralysis** ☐ **Other neurological diagnosis, specify:**

For any neurological event indicated above, check all that apply and provide details in section G.

☐ Depressed/altered level of consciousness/Lethargy/ Personality change lasting ≥24 hrs

☐ Focal or multifocal neurologic sign(s) ☐ Fever (≥38°C) ☐ CSF abnormality ☐ EEG abnormality

☐ EMG abnormality ☐ Neuroimaging abnormality ☐ Brain/spinal cord histopathologic abnormality

First select the neurological event, and then choose corresponding descriptors.

Report "Myoclonic" or "Absence" seizure as "Other neurologic diagnosis, specify".

Report "Myelitis/Transverse myelitis, ADEM or SSPE" as "Other neurological diagnosis, specify"

Report "Anaesthesia/ Paraesthesia" and associated descriptors as "Other neurological diagnosis, specify"

Report Vaccine-associate Paralytic Poliomyelitis as "Other paralysis"

Adverse Event Following Immunization (AEFI)
Case Report Form

Panorama Data Entry Guidance

E. AEFI DETAILS *continued*

Other defined events of interest

Onset: Min. Hrs. Days from immunization to onset of 1st symptom/sign

Duration: Min. Hrs. Days from 1st symptom/sign to resolution of all symptoms/signs ☐ Unresolved

☐ **Hypotonic-Hyporesponsive Episode* (age <2 years):**
- ☐ Limpness ☐ Pallor/cyanosis ☐ Reduced responsiveness/unresponsiveness

☐ **Persistent crying** (continuous and unaltered crying for ≥3 hours)

☐ **Rash:** (Refer to Immunization Manual, Section IX for reporting criteria. For rash at injection site or rash in allergic reaction, use sections above.)
- ☐ Generalized ☐ Localized at non-injection site

☐ **Intussusception***

☐ **Hematochezia**

☐ **Arthritis*:**
- ☐ Joint redness ☐ Joint warm to touch ☐ Joint swelling ☐ Inflammatory changes in synovial fluid

☐ **Parotitis*** (Parotid gland swelling with pain and/or tenderness)

☐ **Orchitis***

☐ **Thrombocytopenia*:**
- ☐ Platelet count <150×10^9/L ☐ Petechial rash ☐ Other clinical evidence of bleeding

☐ **Fever ≥38°C** (Report **only** if fever occurs in conjunction with reportable event. For a neurological event use section above.)

☐ **Syncope with injury**

☐ **Severe vomiting/diarrhea**

☐ **Other serious or unexpected event(s) not listed above** (Specify and provide details in section G):

For tips on reporting rash see Section I.

Report: "Severe vomiting/ diarrhea", "Orchitis", "Hematochezia", or "Syncope with injury" as "Other severe events" and specify in comment field No. 58

Report "Petechial rash" in comment section No. 58.

E. IMPACT OF AEFI, OUTCOME, AND LEVEL OF CARE OBTAINED

Highest impact of AEFI (Choose one of the following):
- ☐ Did not interfere with daily activities
- ☐ Interfered but did not prevent daily activities
- ☐ Prevented daily activities

Outcome at time of report (Choose one of the following):
- ☐ Permanent disability/incapacity ☐ Fully recovered
- ☐ Not yet recovered ☐ Unknown
- ☐ Death; specify date: *YYYY/MM/DD*

Highest level of care obtained (Choose one of the following):

☐ Emergency visit ☐ Non-urgent visit ☐ Telephone advice from a health professional ☐ None ☐ Unknown

☐ Admitted to Hospital (days) **OR** ☐ Resulted in prolongation of existing hospitalization (by days)

Hospital name:

Hospital admission date: *YYYY / MM / DD* Hospital discharge date: *YYYY / MM / DD*

Treatment received: ☐ No ☐ Unknown ☐ Yes (If **yes**, provide details of treatment, including self treatments, in section G.)

See Section I if outcome is fatal.

Report assessment in an emergency room setting without formal admission to hospital as "Emergency Visit".

Date fields for admission and discharge are visible when "Admitted to Hospital" or "Resulted in prolongation" are selected. Otherwise enter dates of care in comment field No. 63.

F. PUBLIC HEALTH RECOMMENDATIONS (Provide comments. Use section G if extra space is required.)

- ☐ No change to immunization schedule
- ☐ Determine protective antibody level, specify:
- ☐ No further immunizations, specify:
- ☐ Other, specify:
- ☐ Expert referral, specify:
- ☐ Controlled setting for next immunization, specify:
- ☐ Active follow up for AEFI recurrent after next vaccine, specify:
- ☐ No recommendations

Name: Professional status: ☐ MOH/MHO ☐ MD ☐ RN ☐ Other, specify:

Comments:

Phone: ( ) ext. Date *YYYY / MM / DD* **Signature:**

Send a copy to: ☐ BCCDC ☐ Client's Physician ☐ Other: _____

See Section I for tips on the "Assigned to" section.

Leave "Last Review Date" and "Eligible for reporting to PHAC" blank.

Select "On behalf of Health Service Provider" if the user is entering the recommendations on behalf of another provider.

G. SUPPLEMENTARY INFORMATION
Please indicate the section number when providing details.
Provide details of any investigation or treatment for the recorded AEFI. Provide sufficient information to support the selected item(s). Append information on additional pages if required.

	In Panorama enter the comments into the AEFI details section of the reaction type, ie. Local, Allergic, etc. using the section-specific comment fields.

H. ADVERSE EVENTS FOLLOWING IMMUNIZATION – TEMPORAL CRITERIA

The length of time between vaccine administration and onset of symptoms is an important consideration in causality assessment. Temporal criteria guidelines in this table are generally agreed upon approximate timelines.

Reaction Type	Adverse Event Following Immunization	Temporal Criteria	
		Inactivated Vaccines	Live Attenuated Vaccines
Local Reactions at Injection Site	Infected Abscess	0-7 days	
	Sterile Abscess	0-7 days	
	Cellulitis	0-7 days	
	Nodule	0-7 days	
	Pain or Redness or Swelling	0-48 hours	
Systemic Reactions	Adenopathy/Lymphadenopathy	0-7 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Fever	Timing in conjunction with other reportable adverse events	
	Hypotonic-Hyporesponsive Episode (HHE)	0-48 hours	
	Parotitis	Not applicable	MMR: 5-30 days
	Orchitis	Not applicable	MMR: 5-30 days
	Rash	0-7 days	MMR: 0 - 30 days Varicella: 0 - 42 days
	Screaming/Persistent crying	0-72 hours	
	Severe Vomiting/Diarrhea	0-72 hours	Rotavirus: 0-7 days
Allergic Reactions	Anaphylaxis	0-24 hours	
	Oculo-respiratory Syndrome (ORS)	0-24 hours	
	Other Allergic Reactions	0-48 hours	
Neurological Events	Anaesthesia/Paraethesia	0-15 days	MMR: 0 - 30 days Varicella: 0 - 42 days
	Bell's Palsy	0-3 months	
	Convulsion/Seizure	0-72 hours	MMR: 5 - 30 days Varicella: 5 - 42 days
	Encephalopathy or Encephalitis or Acute Disseminated Encephalomyelitis (ADEM)	0-42 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Guillain-Barré syndrome (GBS)	0-8 weeks	
	Meningitis	0-15 days	MMR: 5 - 30 days Varicella: 5 - 42 days
	Subacute sclerosing panencephalitis (SSPE)	Not applicable	Up to 10 years following a measles-containing vaccine
	Paralysis	0-15 days	OPV: 5 - 30 days Varicella: 5-42 days
Other Events of Interest	Arthritis	0-30 days	MMR: 5 - 30 days Varicella: 0 - 42 days
	Intussusception or Haematochezia	Not applicable	Rotavirus: 0-42 days
	Syncope with injury	0-30 minutes	
	Thrombocytopenia	0-30 days	
	Other severe or unusual	A temporal association to immunization and for which there is no other known cause and not covered under the other categories	

I. PANORAMA DATA ENTRY DETAILS

Localized rash at the injection site: Local reaction at or near injection site > Other, Specify > Rash

Localized allergic rash: Anaphylaxis and other allergic events > Skin/mucosal > Localized > Select "At injection site" or "Non-injection site" > Specify rash in comment field No. 34

Generalized allergic rash: Anaphylaxis and other allergic events > Skin/mucosal > Generalized > Select "At injection site" and/or "Non-injection site" > Specify rash in comment field No. 34

Generalized rash: Other defined events of interest > Rash > Generalized

Localized rash at non-injection site: Other defined events of interest > Rash > Localized a non-injection site

Pain, redness, or swelling only reportable if meets one or both of the following:
A) Pain, redness, or swelling extends past the nearest joint
B) Pain or redness or swelling persists 10 days or more

Report A) as: Local reaction at or near injection site > Reaction crosses joint > Select appropriate symptoms.
Report B) as: Local reaction at or near injection site > Other local, specify > Select appropriate symptoms.

Also ensure that Duration and Highest Impact of AEFI are provided.

If the ***outcome is fatal***, record as follows.

Outcome at time of report: Death
Outcome Date: Date of death (if known) or date at which user found out about fatal outcome (if date of death unknown)
Also enter date of death in client's demographics in Panorama.

After recording the outcome, inactivate the client in the Personal Information screen (under Subject > Client Details on the left hand navigation) following routine procedures/standards.

Section 10.0 'Assigned to'

The "Assigned to" section must be submitted in order to move to the "11.0 Public Health Recommendations" section. See Panorama AEFI Data Entry Guide for more information.

If the medical health officer requires a consultation from BCCDC Immunization Programs and Vaccine Preventable Diseases Service, email Dr. Monika Naus (monika.naus@bccdc.ca) and include the client ID and Adverse Event ID in your email; do not use the 'assigned to' function within Panorama for this purpose.

NOTE: Additional relevant training materials and data standards are available on the Panorama Solution Partner Portal (https://panoramacst.gov.bc.ca).